REMARKS

Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 were pending and examined in the Office Action dated July 9, 2007. Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 were rejected in that eighth non-final Office Action. No claims have been added, modified, or deleted by this Response. Applicants respectfully request reconsideration of this application.

REJECTIONS UNDER 35 U.S.C. § 102

Claim 1 stands rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by Doore et al. (4,012,795). To establish a *prima facie* case of anticipation, the Examiner must show that the prior art reference teaches each and every claim limitation of Applicants' independent claim, which has not been done. Applicants' claim 1 recites "a metal alloy substrate having an average grain size in the range of one to ten microns." The Doore `795 patent teaches a medical device configured from aluminum oxide, a ceramic (col. 2, lines 27-38). As the Examiner should appreciate, metal oxides and ceramics do not anticipate a metal alloy as presently claimed. Thus, Applicants respectfully submit that the rejection of Applicants' claim 1 under § 102(b) is improper and must be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 1-9, 14-16, 22-24, 26-29, 41-43, and 45 stand rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Frantzen (5,843,175) in view of Reimann et al. (3,723,193). The Frantzen `175 patent discloses a medical device, namely a stent, made from a metal alloy, for example, stainless steel. As the Examiner acknowledges, the Frantzen `175 patent does not teach that the disclosed stent is made from a material (substrate) that has an average grain size of one to ten microns. The Examiner further

notes that Frantzen `175 does not anticipate several of the limitations in Applicants' dependent claims. The Reimann `193 patent discloses processing a metal alloy, such as stainless steel, to produce a fine grain tubing having a randomly-distributed precipitate (for example, a carbide) dispersed throughout the structure for use in a cladding for nuclear reactor fuel rods. Neither cited reference teaches or suggests a medical device formed from a fine grain metal alloy substrate, as claimed by Applicants.

Applicants submit that the combination of the teachings of the Frantzen `175 and Reimann `193 patents does not enable a "medical device" comprising "a metal alloy substrate having an average grain size in the range of one to ten microns," as recited in Applicants' independent claim 1, and its dependent claims 3-10, 14-16. Although Frantzen `175 discloses a medical device, the fine grain substrates disclosed by Reimann `193 are unsuitable for use as a substrate for forming a medical device, such as a stent. Reimann `193 discloses producing a fine grain stainless steel alloy (Type 316) having randomly-distributed discrete carbide particles dispersed throughout the structure (see col. 2, lines 27-52). Carbide laden Type 316 stainless steel is unsuitable for use in a medical device, which is likely why Frantzen `175 recites using Type 316L stainless steel. Similarly, one having ordinary skill in the art would know that aluminum is not a biocompatible material and would not combine the aluminum alloy teachings of Reimann `193 in combination with the medical device of Frantzen `175.

The Examiner's statement that it would have been obvious to one having ordinary skill in the art in view of Reimann `193 to form the substrate of Frantzen `175 out of fine grain Type 316L stainless steel is unsupported and clearly wrong. Reimann `193 does not teach how to make fine grain Type 316L stainless steel, but uses Type 316 stainless steel in its Examples. Type 316 stainless steel is unsuitable for use in medical devices, so there would be no motivation to combine the teachings of Reimann `193 with Frantzen `175. There is no indication that the process taught in the Reimann `193 patent would produce a fine grain substrate from a biocompatible metal alloy. Accordingly, the teachings of Reimann `193 do not provide the benefit of "improved ductility for the

medical device or stent" to solve the problem with Frantzen `175 proposed by the Examiner. Although it is known in the art that the distributed carbides referred to in Reimann `193 function to improve the 316 stainless steel material's resistance to radiation damage by acting as vacancy sinks, such enhancements of the material are not relevant to forming a substrate for use in a medical device.

Moreover, the Examiner's statement that the material formed by the process of Reimann `193 when used in a medical device (for example, a stent) "would not readily break upon expansion" is unsupported by the disclosure. Those having ordinary skill in the art would recognize that such randomly-distributed discrete particles, such as carbide precipitates in 316 stainless steel, would likely introduce deformation problems in intentionally deformable medical device structures. The distributed precipitates result in increased strength, which in turn would not allow proper functioning of a device formed from this alloy with respect to mechanical deformations (for example, such as crimping and expansion) necessary for a stent and other medical devices. At a minimum, the recoil of the device would be such that it would not stay securely on a balloon catheter. At a maximum, the device would not be expandable by a balloon. Such a problem would be especially apparent when forming an element of a medical device (for example, a stent strut) with five to fifteen grains across a thickness of the element (claims 14-16). Further, Reimann `193 discloses tubing having an outer diameter in the range of 0.25 to 1.5 inches (col. 2, line 68; col. 5, line 16), which is orders of magnitudes greater than most elements of a medical device.

In addition, the teachings in Reimann `193 are specifically limited to metal alloys that will provide a precipitate when the alloy is heated to solution. Type 316L stainless steel (claims 4-5) does not produce a carbide precipitate as does the Type 316 stainless steel used in the Reimann Examples (the Examiner erroneously states that Reimann `193 patent teaches using Type 316L stainless steel). The Reimann `193 patent also mentions using aluminum alloys (col. 2, line 39), which are unsuitable for use in the human body. Moreover, precipitates formed from biocompatible metal alloys such as

cobalt-chromium, nickel-titanium, platinum-iridium, titanium and tantalum that are recited in Applicants' claims 6-10 would not be intentionally introduced into a medical device by one having ordinary skill in the art as would be required by modifying the stent of Frantzen `175 with the teachings of Reimann `193. Accordingly, Applicants respectfully submit that the Examiner's statement that it would be "a matter of obvious design choice" to substitute a known biocompatible material for the alloys taught by Reimann `193 is contrary to how one having ordinary skill in the art would use such materials containing intentionally introduced precipitates.

Furthermore, Applicants respectfully submit that it is the burden of the Examiner to apply each of the elements of Graham, including identifying the level ordinary skill in the art, which has not been done -- see MPEP §§ 2141, 2141.03. It is noteworthy that although the Reimann `193 patent issued in 1973, that its teachings, directed to use in atomic energy applications, have not been applied to medical devices during the past 35 years. This lack of applying the disclosure of Reimann `193 to solve a long felt need in the art for a fine grain medical device suggests the unsuitability and non-obviousness of such intentionally precipitate laden alloys for use as a medical grade substrate. There is no reasonable expectation that one having ordinary skill in the art could use the teachings of Reimann `193, which are limited to forming participate laden alloys, so as to produce a fine grain metal alloy suitable for use in a medical device.

Similarly, Frantzen `175 and Reimann `193 do not enable forming cylindrical rings of an intravascular stent from a fine grained medical grade material as recited in Applicants' independent claim 22 and dependent claims 23-24, 26-29. Likewise, the combination of the cited references does not disclose a stent formed from a suitable substrate having an average grain size of one to ten microns, as recited in Applicants' independent claim 41 and dependent claims 42-45. Thus, Frantzen `175 and Reimann `193 when applied by one having ordinary skill in the art in forming a substrate do not render Applicants' independent claims obvious.

Claim 10 stands rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Frantzen `175 in view of Reimann `193 further in view of Kumar et al. (5,171,379). The Kumar `379 patent does nothing to solve the deficiencies of Frantzen `175 and Reimann `193. As explained above, the Examiner's combination of Frantzen `175 and Reimann `193 does not render obvious Applicants' claim 1, from which claim 10 depends. In addition, Kumar `379 teaches sintering tantalum with silicon, thorium and other metallic/non-metallic doping agents. There is no teaching that the doped tantalum materials are suitable for use in a medical device as claimed by Applicants so as to render the claim obvious by the combination of references applied by the Examiner.

Claim 44 stands rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Frantzen `175 in view of Zhu et al (5,171,379). The Zhu `215 patent does nothing to solve the deficiencies of Frantzen `175 identified by the Examiner. Therefore, the combination of references does not render the claim obvious. As Applicants have repeatedly pointed out in their responses to prior Office Actions, the Zhu `215 patent discloses processing commercially pure titanium (col. 4, lines 28-30) to provide a billet of "ultrafine-grained titanium." No starting materials other than commercially pure titanium are disclosed in the Zhu `215 patent. Thus, neither cited reference teaches or suggests a metal alloy having an average grain size in the range of one to ten microns so as to teach each element of Applicants' claim and render it obvious.

Accordingly, Applicants respectfully submit that the rejections of Applicants' claims under § 103(a) is improper and should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe that all presently pending claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 are in condition for allowance, and that the application should be passed to issue. The Examiner is encouraged to contact the undersigned should there be any questions or resolvable matters regarding this application.

Respectfully submitted,

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